JC998 NOV 24 2003 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):	RUBINSTEIN, Abraham et al.	EXAMINER:	WEBMAN, E.
SERIAL NO.:	10/630,917	GROUP ART UNIT:	Not yet known
FILED:	November 20, 2003	Attorney Docket No.:	P-4798-US3
FOR.:	CONTROLLED RELEASE ORAL DRUG DELIVERY SYSTEM		

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO-1449:

1. ☒ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
2. ☒ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. 08/750,674, filed 13-Jun-95 which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the

listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I) ☒ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

II) ☐ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of $180.00 under 37 C.F.R §1.17 (p) to Deposit Account 05-0649.

III) ☐ After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:

a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☐ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of $180.00 under 37 C.F.R §1.17 (p) to Deposit Account 05-0649.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 05-0649.

Respectfully submitted,

Mark S. Cohen
Attorney for Applicant(s)
Registration No. 42425

Dated: November 20, 2003

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

Complete if Known	
Application Number	10/630,917
Filing Date	Nov mber 20, 2003
First Named Inventor	RUBINSTEIN, Abraham
Group Art Unit	Not yet known
Examiner Name	WEBMAN, E.
Attorney Docket Number	P-4798-US3

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	4,568,559		NUWAYSER et al.	Feb. 4, 1986	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	AB	DD	252539A1		Europe	Dec 1987		☐

Examiner Signature		Date Considered	

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[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 5

Complete if Known	
Application Number	10/630,917
Filing Date	November 20, 2003
First Named Inventor	RUBINSTEIN, Abraham
Group Art Unit	Not yet known
Examiner Name	WEBMAN, E.
Attorney Docket Number	P-4798-US3

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	AC	BATTAGLIA, E., et al., "Characterization of a New Class of Inhibitors of the Recombinant Human Liver UDP-Glucuronosyltransferase, UGT1*6, Biochimica et Biophysica Acta, 1243 : 9-14 (1995)	☐
	AD	BENET, L.Z., et al., "Importance of Drug Metabolism and Antitransport Processes: A Paradigm Shift in Oral Drug Delivery," Proceedings of the 7th International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, Utah, pp 11-14 (1995)	☐
	AE	BORCHARD, G., et al., "Multifunctional Polymers for Improved Peroral Peptide Drug Absorpton," Proceedings of the 7th International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, Utah, pp 7-10, Bai J. P-F., et al. ibit., pp 153-154 (1995).	☐
	AF	CHAO, Y.W. and FLYNN, M., "Oral Delivery of Insulin," Lancet, 23 : 1518-1519 (1989).	☐
	AG	DAMGÉ, C., et al., "New Approach for Oral Administration of Insulin with Polyalkylcyanoacrylate Nanocapsules as Drug Carrier," Diabetes, 37 : 246-251 (1988).	☐
	AH	DANFORTH, JR., E. and MOORE, R.O., "Intestinal Absorpton of Insulin in the Rat," Endocrinology, 65 : 118-123 (1959).	☐
	AI	DAPERGOLAS, G. and GREGORIADIS, "Hypoglyaemic Effect of Liposome-Entrapped Insulin Administered Intragastrically into Rats," Lancet, 2 : 824-827 (1976).	☐
	AJ	Eudragit® RL Data Sheet (Info RL-3/e). No date given.	☐
	AK	Eudragit® RL/RS Standards Sheet (Info RL/RS-7/e). No date given.	☐
	AL	Eudragit® RL/RS Technical Application Pamphlet (Info RL/RS-11/e). No date given.	☐
	AM	Eudragit® RL/RS Technical Application Pamphlet (Info RL/RS-12/e). No date given.	☐
	AN	Eudragit® RL and RS Application in the Production of Pharmaceutical Preparations Prospectus (Info RL/RS-1/e). No date given	☐

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Sheet 3 of 5

Application Number	10/630,917
Filing Date	November 20, 2003
First Named Inventor	RUBINSTEIN, Abraham
Group Art Unit	Not yet kn wn
Examiner Name	WEBMAN, E
Attorney Docket Number	P-4798-US3

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NON PATENT LITERATURE DOCUMENTS

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	AO	FAHR, A., "Cyclosporin Clinical Pharmacokinetics," Clin. Pharmacokinet., 24(6) : 472-495 (1993)	☐
	AP	GEARY, R.S. and SCHLAMEUS, H.W., "Vancomycin and Insulin Used as Models for Oral Delivery of Peptides," J. Controlled Release, 23 : 65-74 (1993)	☐
	AQ	GORIYA, Y., et al., "Blood Glucose Control and Insulin Clearance in Unrestrained Diabetic Dogs Portally Infused with a Portable Insulin Delivery System," Diabetologia, 19 : 452-457 (1980)	☐
	AR	HOCHMAN, J.H., et al., "In vitro and In Vivo Analysis of the Mechanism of Absorption Enhancement by Palmitoylcarnitine," J. Parm. and Exp. Therap., 269 (2) : 813-822 (1994)	☐
	AS	HOCHMAN, J. and ARTURSSON, P., "Mechanisms of Absorption Enhancement and Tight Junction Regulation," J. Controlled Release, 29 : 256-267 (1994)	☐
	AT	HONESCH, H., et al., "Cytochrome P-450 and Drug Metabolism in Intestinal Villous and Crypt Cells of Rats: Effect of Dietary Iron," Biochem and Biophys. Res. Comm., 65(1) : 399-406 (1975)	☐
	AU	KIDRON, M., et al., "The Absorption of Insulin From Various Regions of the Rat Intestine," Life Science, 31 (25) : 2837-2841 (1982).	☐
	AV	KRAELING, M.E.K. and RITSCHEL, W.A., "Development of a Colonic Release Capsule Dosage Form and the Absorption of Insulin," Meth Find Exp. Clin. Pharmacol., 14(3) : 199-209 (1992)	☐
	AW	LEE, V.H.L., et al., "Oral Route of Peptide and Protein Drug Delivery," V.H.L. Lee (Ed.) : Peptide and Protein Drug Delivery, Marcel Dkker, 1991 New York, pp 691-738.	☐
	AX	MORISHITA, M., et al., "Novel Oral Microspheres of Insulin With Protease Inhibitor Protecting From Enzymatic Degradation," Intl. J. Pharmaceutics, 78 : 1-7 (1992).	☐
	AY	MURANISHI, S., "Absorption Enhancers," Critical Reviews in Therapeutic Drug Carrier Systems, 7(1) : 1-34 (1990)	☐
	AZ	OSBORNE, R., et al., "Morphine and Metabolite Behavior After Different Routes of Morphine Administration: Demonstration of the Importance of the Active Metabolite Morphine-6-Glucuronide," Clin. Pharmacol, Ther., 47(1) : 12-19 (1990)	☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 5

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Application Number	10/630,917
Filing Date	November 20, 2003
First Named Inventor	RUBINSTEIN, Abraham
Group Art Unit	Not yet known
Examiner Name	WEBMAN, E.
Attorney Docket Number	P-4798-US3

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	AA2	PATEL, H.M. and RYMAN, B.E., "Oral Administration of Insulin by Encapsulation Within Liposomes," FEBS Letters, 26(1) : 60-63 (1976)	☐
	AB2	PETERS, W.H.M., et al., "Glutathione S-Transferase, Cytochrome P450, and Uridine 5' – Diphosphate-Glucuronosyltransferase in Human Small Intestine and Liver," Gastroenterology, 96 : 783-789 (1989)	☐
	AC2	SAFFRAN, M., et al., "A New Approach to the Oral Administration of Insulin and other Peptide Drugs," Science, 233 : 1081-1084 (1986)	☐
	AD2	SANDERS, L.M., et al., "Prolonged Controlled-Release of Nafarelin, A Luteinizing Hormone-Releasing Hormone Analogue, From Biodegradable Polymeric Implants: Influence of Composition and Molecular Weight of Polymer," J. Pharm. Sci., 75(4) : 356-360 (1986)	☐
	AE2	SANDERS, L.M., et al., "Controlled Delivery of an LHRH Analogue From Bjodegradable Injectable Microspheres," J. Controlled Release, 2 : 187-195 (1985).	☐
	AF2	SCHULTE-HERMANN, R. and PARZEFALL, W., "Adaptive Responses of Ra Liver to the Gestagen and Anti-Androgen Cyproterone Acetate and other Inducers. I. Induction of Drug-Metabolizing Enzymes," Chem Biol. Interactions, 31 : 279-286 (1980).	☐
	AG2	TAKAHASHI, K., et al., "Decanoic Acid Induced Enhancement of Rectal Absorption of Hydrophilic Compounds in Rats," Pharmaceutical Res., 11(10) : 1401-1404 (1994)	☐
	AH2	TAKAHASHI, K., et al., "Pharmacokinetics Analysis of the Absorption Enhancing Action of Decanoic Acid and its Derivatives in Rats," Pharm. Res., 11(3) : 388-392 (1994).	☐
	AI2	TOUITOU, E. and RUBINSTEIN, A., "Targeted Enteral Delivery of Insulin to Rate," Intl. J. Pharm., 30 : 95-99 (1986)	☐
	AJ2	VAN HOOGDALEM, E.J., et al., "Intestinal Drug Absorption Enhancement: an Overview," Pharmac, Ther., 44 : 407-443 (1989)	☐
	AK2	WAHLSTRÖM, A., et al., "Tricyclic Antidepressants Inhibit Opioid.. Receptor Binding in Human Brain and Hepatic Morphine Glucuronidation," Phar. & Toxic., 75 : 23-27 (1994).	☐

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Sheet 5 of 5

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Filing Date	November 20, 2003
First Named Inventor	RUBINSTEIN, Abraham
Group Art Unit	Not yet known
Examiner Name	WEBMAN, E.
Attorney Docket Number	P-4798-US3

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NON PATENT LITERATURE DOCUMENTS

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	AL2	WEINGARTEN, C., et al., "Oral Ingestion of Insulin Liposomes: Effects on the Administration Route," Life Science, 28 : 2747-2752 (1981)	☐
	AM2	ZIV, W., et al., "Absorption of Protein via the Intestinal Wall, Bochem. Pharmcol, 36(7) : 1035-1039 (1987)	☐
	AN2	Database WPI, Week 9530, Derwent Publications Ltd., London, GB; AN 95-228636 & JP, A, 07 138 182 (TOYOBO et al.), 30 May 1995 Abstract.	☐
			☐

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